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Docket No. USF-221XT
Serial No. 09/763,419Remarks

Claims 1-6 and 8-20 are pending in the subject application. By the previous May 11, 2005 Amendment, Applicants have canceled claims 1-6 and 8-20 and rewritten them as new claims 21-40. In Section 3 of the Advisory Action dated May 20, 2005, the Examiner indicates that Applicants' Amendment submitted May 11, 2005 would not be entered because it raises new issues that would require further consideration and/or search and raises the issue of new matter. Entry and consideration of the amendments presented therein is respectfully requested in view of the attached Request for Continued Examination. Upon entry of the above amendments, claims 21-40 will be before the Examiner.

Claims 1-6 and 8-20 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description purportedly because the exclusion of a cross-linked organic ligand has no basis in the specification. Also, Section 11 of the Advisory Action indicates that the instant application "does not convey to one of ordinary skill in the art that cross-linking is excluded from the process of preparing the columns." Applicants traverse this rejection because the skilled artisan would understand that the organic ligands, or the organic-inorganic composites, are not cross-linked when reading the specification in view of the prior art. There is no requirement that the claim terminology must be present verbatim in the specification. It is well settled in patent law that the claim language of an amendment need not be disclosed word for word in a specification. *In re Wilder*, 222 USPQ 369, 372 (Fed. Cir. 1984) ("It is not necessary that the claimed subject matter be described identically, but the disclosure must convey to those skilled in the art that applicant had invented the subject matter later claimed.") (emphasis added); see also MPEP §2163.02.

Applicants respectfully point out that the specification includes several schemes that illustrate the deactivation of the column at the inner surface and embodiments for the formation of the columns and methods of the claimed invention. However, to expedite prosecution, Applicants attach a Declaration under 37 CFR 1.132 and an Exhibit A that establish the understanding of the skilled artisan that the columns prepared in accordance with the subject invention would not have cross-

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linked sol-gel coatings. The Declarant, who is also a co-inventor of the current invention, submits that;

a skilled artisan would understand that the organic ligands in the method claims, or the organic-inorganic composites in the column claims, are not cross-linked when reading the specification in view of the prior art. First, the specification includes several schemes that illustrate the deactivation of the column at the inner surface and embodiments for the formation of the columns and methods of the claimed invention. A skilled artisan viewing methods to prepare GC stationary phase coatings that do use cross-linking reagents would understand that the sol-gel coating of the claimed invention could not possess a cross-linked organic ligand. Second, the specification itself discusses the advantages of the claimed invention, one of which is its lack of free radical cross-linking reactions (page 28, line 14). The column would have no mechanism by which an organic polymer could cross-link. Thus, the skilled artisan would understand that the columns are prepared without cross-linking the organic ligands in the column coating.

(page 2, §11) (emphasis in original). In view of the supplemental remarks, Declaration under 37 CFR 1.132, and Exhibit A along with the remarks of amendments of May 11, 2005, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-6 and 8-20 are rejected under 35 U.S.C. §103(a) as obvious over the Hayes *et al.* article (hereinafter 'Hayes *et al.* 1997') in view of Ogden *et al.* (1986) and Sumpter *et al.* (1990), and optionally Hayes *et al.* (hereinafter 'Hayes *et al.* 1996') and Wang *et al.* (1996). The Hayes *et al.* 1997 article fails to teach or suggest the claimed columns or methods of preparing the claimed columns. Hayes *et al.* 1997 pertains to a capillary electrophoresis (CE) column. Although the Hayes *et al.* 1997 CE column does possess a sol-gel coating, its sol-gel coating is inapplicable to columns of the claimed invention according to Dr. Malik, the Declarant, for the following reasons:

First, the Hayes *et al.* 1997 coatings possess highly cross-linked polymers to prevent the analyte molecules from interacting with the solute, thereby reducing separation efficiency. Second, the skilled artisan is not motivated to apply the Hayes *et al.* 1997 sol-gel coating to the gas chromatographic (GC) columns of the claimed invention because the highly cross-linked polymer coatings of Hayes *et al.* 1997 would result in poor solute diffusion and mass transfer of the analyte molecules.

Third, the CE column is not used to separate moieties chromatographically. By its definition, a CE column possess only a mobile phase and takes advantage of migration rates of ionic solutes in a liquid mobile phase environment when they are

placed in an electric field. When these solutes are exposed to the inner surface of the column, any resulting interactions reduce the column efficiency. Any sol-gel coating applied to a CTE column does not represent a stationary phase where separation of ionic analytes takes place because of differences in their electrophoretic migration rates in an electric field. As noted above, the sol-gel coating is applied only to prevent unwanted interactions between the solutes and the inner surface of the capillary. Fourth, the sol-gel coating of the Hayes *et al.* 1997 columns contains a highly cross-linked organic ligand. In contrast, the deactivated sol-gel stationary-phase coating of the claimed invention contains a chemically bonded non-crosslinked ligand.

(page 3, §III) (emphasis in original). The Ogden *et al.* article fails to remedy the deficiencies of Hayes *et al.* 1997. For one, the skilled artisan would not combine the teachings of Hayes *et al.* 1997 with the Ogden *et al.* article because the individual columns rely on two distinct separation theories. As discussed above, Hayes *et al.* 1997 fails to even have a stationary phase within its column. Furthermore, whereas Hayes *et al.* 1997 relies on the migration rates of various ionic liquid solutes, Ogden *et al.* uses a conventional coating as a stationary phase.

The combined teachings of Hayes *et al.* 1997 and Ogden *et al.* do not teach or suggest the claimed invention. As noted above, the current invention does not possess cross-linked elements. Both Hayes *et al.* 1997 and Ogden *et al.* teach cross-linked coatings of their individual columns. Furthermore, the Ogden *et al.* coatings do not exhibit the extent of deactivation exhibited in the current invention. The Ogden *et al.*'s coatings are deactivated only at the surface of the capillary (pages 16-7). In contrast, the claimed column, advantageously, possesses a deactivated sol-gel coating, which encompasses both the deactivation at the tube inner surface and throughout the coating.

Regarding the methods of the claimed invention, the Ogden *et al.* article relies on a multi-step approach in the preparation of its columns, wherein the deactivation step takes places separately from the immobilization step (pages 11-3). In contrast, the stationary phase of the claimed invention is created, coated, immobilized, and deactivated in one step.

Again, the skilled artisan is unlikely to combine the teachings of Sumpter *et al.* with Hayes *et al.* 1997. According to the Declarant:

Sumpter *et al.*, similar to Ogden *et al.* discussed above, pertains to chromatographic columns (gas and supercritical fluid). The skilled artisan has no motivation to

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combine the teachings of a separation column based on chromatography with a separation column based on migration rates of ionic solutes in a liquid mobile phase environment. As noted above, sol-gel coatings in chromatographic columns are used as a stationary phase whose differential interactions with the analytes lead to separation. In contrast, the sol-gel coating in Hayes *et al.* 1997 is used to prevent interactions between the column and the solute.

(page 4, §III). Even if the references were properly combinable, the combination of Hayes *et al.* 1997 in view of Sumpter *et al.* or the combination of Hayes *et al.* 1997 in view of Ogden *et al.* and Sumpter *et al.* fails to teach each and every element of the claimed invention. Regarding the method claims, the combination of references fails to teach a preparation of sol-gel coatings wherein the creation, the coating, the immobilization, and the deactivation take place all in one step. Specifically, the methods disclosed in the cited references are multi-step preparations.

Regarding the columns itself, the combined references again fail to teach a column with a deactivated sol-gel coating. As noted above, Hayes *et al.* 1997 only deactivates at the surface while shielding any residual sites within its column, and both the Ogden *et al.* and Sumpter *et al.* only teach deactivation at their respective column surfaces. Thus, the combination of references fails to teach or suggest a GC column with a sol-gel coating stationary phase coating that is deactivated at both the inner surface and within the coating. Thus, Applicants respectfully request reconsideration and withdrawal of this aspect of the 35 USC §103(a) rejection in view of the remarks above, the attached Declaration under 37 CFR 1.132, and the May 11, 2005 Amendment.

The Wang *et al.* reference also fails to remedy the short-comings of Hayes *et al.* 1997. For one, the Wang *et al.* reference is directed to a non-aqueous preparation for a sol-gel coated GC column. In contrast, the Hayes *et al.* 1997 column is directed to an aqueous preparation for a sol-gel coated GC column. Wang *et al.* teaches against aqueous preparation of GC columns (page 507). The Declarant, who is a co-author of both the Wang *et al.* reference and the Hayes *et al.* 1996 and 1997 articles, sets forth in his Declaration that

the skilled artisan understands that due to the innate differences in aqueous prepped GC columns and non-aqueous-prepped columns, the resulting column perform inefficiently, if at all (see, for example, Figure 2 from Wang *et al.* vs. Figures 31 and 36 of the subject application). In contrast, the columns of the claimed invention unexpectedly show highly efficient separations represented by narrow peaks that are narrow without the tailing exhibited by the Wang *et al.* column. Evidence supporting

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this superior separation column can be found throughout the instant application including, for example, Figures 7-39.

(page 5, §111). Accordingly, Applicants respectfully request reconsideration and withdrawal of this aspect of the rejection under 35 USC §103(a).

The Hayes *et al.* 1996 article also does not remedy the deficiencies in the Hayes *et al.* 1997 article. Dr. Malik sets forth his rationale why the combination of Hayes *et al.* 1997 and Hayes *et al.* 1996 does not teach or suggest the current invention:

First, Hayes *et al.* 1996 fails to suggest or teach a gas chromatography column having the deactivated surface coating of the claimed invention. The teachings of Hayes *et al.* 1996 apply to a CE column (page 497, lines 32-33). As noted above, the coating in a CE column is used to prevent unwanted interactions between the analyte and the column surface. The CE coating does not function as a stationary phase and fails to provide molecular level interactions responsible for chromatographic separation. Moreover, Hayes *et al.* 1996 only discusses sol-gel techniques as they have been applied to capillary electrochromatography, capillary electrophoresis, and open tubular liquid chromatography (page 500, lines 4-7). It provides no suggestion that a sol-gel coating could be applied to a GC column to separate analytes in a gaseous mobile phase environment.

Second, Hayes *et al.* 1996 fails to suggest that the coating could be prepared in the presence of water. The preparation steps explicitly avoid the use of water or even components having hydrated water molecules. The only disclosure for an aqueous preparation is with respect to a packed column. In contrast, the claimed invention pertains to coated columns. There is no need for a packing in the sol-gel columns of the claimed invention prepared by using an aqueous sol-gel process. Thus, the deficiencies of Hayes *et al.* 1997 are not remedied by the teachings of Hayes *et al.* 1996.

(page 5, §111). Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully requested.


Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

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The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,


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Attachments: Request for Continued Examination Transmittal (PTO/SB/30);
Declaration Under 37 CFR 1.132 by Dr. Abdul Malik;
Exhibit A

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